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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/132,593	08/11/98	SAEBO	A 21440/9015
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EXAMINER

WANG, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

11/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**Office Action Summary**

Application No.

09/132,593

Applicant(s)

SAEBO ET AL.

Examiner

Shengjun Wang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 September 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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### DETAILED ACTION

1. The request filed on September 21, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/132593 is acceptable and a CPA has been established. An action on the CPA follows.

#### *Claim Rejections 35 U.S.C. § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "a conjugated linoleic acid alkyl ester" in claims 4 and 7 is used by the claim to mean "a conjugated linoleic acid alkyl ester composition," while the accepted meaning is "a compound."

4. The term "low" in claim 7 is a relative term which renders the claim indefinite. The term "low" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claim is indefinite as to the temperature encompassed thereby.

#### *Double Patenting Rejections*

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,015,833. Although the conflicting claims are not identical, they are not patentably distinct from each other.

'833 does not particularly claim that the isomerized linoleic acid composition comprising 0.1-0.5 % of phosphatidyl residue or the amount of 9,11 and 10, 12 isomers. However, '833 discloses that the isomerized linoleic acid composition contains about 0.4-1% of phosphatidyl residue and the particular amount of 9,11 and 10, 12 isomers herein. See, particularly, the tables in '833.

### ***Claim Rejections 35 U.S.C. § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-8 rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,554,646 of record) and Cook et al. (US 5,428,072 of record) in view of Chin et al. (IDS, November 23, 1999).

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Cook'646 teach a active form conjugated linoleic acid, i.e., 10,12-octadecadienoic acid and 9,10-octadecadienoic acid, which including ester, salt and free acid of conjugated linoleic acid. See. Particularly, column 1 lines 65-67, column 2, line 1 and column 4, lines 1-9. Cook'646 further teach a animal feeding comprising the said active form of conjugated linoleic acid. See, particularly, column 1, lines 39-60 and examples 1-4. The feeding can also comprising phosphotides. See, column 5, line 47. Cook'646 also teach a safe and effective method for reducing body fat in animal by administering the said animal feed. See, particularly, the abstract. c9,t11- and t10,c12- isomer are predominantly major isomer of the conjugated linoleic acid active form of Cook'646. See, particularly, column 4, lines 50-55. Cook'072 teach a method of increasing the feed efficiency in an animal which comprises administering to the animal a safe and effective amount of conjugated linoleic acid. See, the abstract.

Cook et al. do not teach expressly the conjugated linoleic acid active form further comprising the regio isomers 8,10- and an 11,13- octadecadienoic acid derivative.

However, since the preferred amounts in the applicants claims are limited to less than 2 percent, this amount includes zero percent of the regio isomers. Thus, Cook' teachings meet this limitation. Further, Chin et al. teach that it is known that c9,t11- conjugated linoleic acid isomer is a active form of conjugated linoleic acid. See, particularly, page 185, the abstract.

Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a conjugated linoleic ester mixture comprising predominantly c9,t11- and t10, c12-octadecadienoic ester without/or with less than 2% of 8,10- and 11,13- octadecadienoic ester and employ the mixture in animal feed.

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A person of ordinary skill in the art would have been motivated to make a conjugated linoleic ester mixture comprising predominantly c9,t11- and t10, c12-octadecadienoic ester without/or with less than 2% of 8,10- and 11,13- octadecadienoic ester and employ the mixture in animal feed because 8,10- and 11,13- octadecadienoic esters are known not to be required in the active form of conjugated linoleic acid and the c9,t11 and t10,c12 ester mixture is known to be useful in animal feeds.

*Response to The Arguments*

9. Applicants' amendments and remarks submitted September 21, 2000 and the exhibits A and B submitted March 28, 2000 have been fully considered but they are not persuasive as discussed below.

Regarding the remarks that most commercially available CLA compositions also contain 8,10- and 11,13- isomer of conjugated linoleic acid, it is noted that the cited prior art does not disclose the presence of any significant amounts of isomers such as the 8,10- and 11,13- isomer of conjugated linoleic acid in the compositions therein. Further, purification of each individual isomer of conjugated linoleic ester is considered within the skill of artisan, absent the evidence to the contrary. Applicants have not demonstrated any unexpected results, e.g., in the purity of isomers useful herein over the prior art.

Applicants' assertion that the conjugated linoleic acid employed by Cook contains significant amount of 8,10 and 11, 13 regio isomers have been considered but are not persuasive. Every patent is presumed valid. See MPEP 716.07. As discussed above, Cook specifically teach a compositions comprising predominately 9,11 and 10,12 isomers.

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Regarding the remarks of reasonable expectation of success, note the instant claims are directed to compositions. As discussed above, a person of ordinary skill in the art would have been reasonably expected to be successful in making the composition herein since the method of making the composition is not seen to limit the claimed composition.

Regarding the remarks of the unexpected results, note that unexpected results must be support by the comparison of the closest prior art and commensurate in scope with claimed invention. See MPEP 716.02(d) (e). The two references (Sugano et al. and Christie) submitted March 28, 2000 is not the closest prior art. Further, the data presented in the instant application lack the comparative chromatography data of 8, 10 and 11,13 conjugated linoleic isomers and is not convincing that 8, 10 and 11,13 conjugated linoleic isomers are not presents in the compositions herein since the resolution of all these isomers is very poor (8,10 isomer is completely overlap with 9, 11 isomer). See the chromatogram in Christie.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Shengjun Wang

AU 1617

~~July 19, 2000~~

Nov. 25,

RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200